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February 15, 2018

Hon. Claire C. Cecchi, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Bldg. & U.S. Courthouse
Courtroom MLK 5B
50 Walnut Street
Newark, New Jersey 07101

Re: Proton-Pump Inhibitor Products Liability Litigation (No. II); 2:17-md-2789 (CCC)(MF) (MDL 2789)

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Dear Judge Cecchi:

We write in response to the PSC's letter filed on Tuesday regarding alleged discovery issues and delays by AstraZeneca ("AZ"). The PSC's letter is inaccurate and very misleading and while we can address each of the issues the PSC raises, we prefer not to waste the Court's time with issues that are not yet ripe and may be mooted completely as we continue to meet and confer with the PSC. As Your Honor may recall, as early as Spring 2017, AZ warned that the PSC's "MDL playbook" included manufacturing dubious discovery disputes to distract from the merits of the cases. The PSC's letter is an attempt to do just that and should be rejected.

Just to recap: AstraZeneca has been tirelessly working around the clock and, to date, has produced over three and a half million pages of documents; engaged in extensive meet and conferring with Plaintiffs' counsel in good faith to respond to Plaintiffs' 167 separate requests for production of documents and more than 155 Interrogatories (including subparts); and has produced six 30(b)(6) witnesses for deposition and a Rule 26 disclosure statement. Given that Plaintiffs have not yet produced a single sheet of paper in discovery in the MDL, their criticisms of AZ and characterization that AZ intends to delay the process is, quite frankly, ridiculous and belied by the facts.[1] Plaintiffs' issues, many of which were raised for the first time

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[1] To date, the PSC has been reluctant (or unable) to produce the most basic information about the Plaintiffs' alleged claims, including what particular PPI products they took, what their alleged injuries are, and/or why they think Defendants' products caused those injuries. By way of example, the PSC has so far, taken the position that it would take them at least 6 months to prepare for Science Day (*see* Sept. 12, 2017 Status Conf. Tr. at 27:2-14); only Defendants, not Plaintiffs have to produce Rule 26(a) disclosures; producing their medical diagnosis record (their very basis for filing suit) is too burdensome (*see* Plaintiffs' December 13, 2017 letter brief regarding Plaintiffs' proposed Case Management Order Governing the Plaintiff Fact Sheet and PFS Document Production, pp. 5-6); and

last week, are the subject of ongoing meeting and conferring and are therefore not ripe for Court's intervention at this time.

A. Search Terms

To the extent that the time that has transpired can properly be deemed a delay, it has been occasioned by Plaintiffs' ever-changing list of search terms. Plaintiffs' latest iteration of search terms, which for the first time included "stand-alone" search terms such as "Nexi*" and numerous others were first presented to AZ last month. We have been and continue to work extensively to evaluate these terms.

At the last MDL conference, AZ indicated that it would provide metrics relating to some of the overbroad search terms to Plaintiffs once available, and prior to the next status conference. AZ is on target to provide these metrics, but the process is complicated and takes time—including machine time that cannot be expedited—to process, export, copy, transfer, ingest and index the voluminous documents and corresponding searchable text files. Both AZ's internal discovery group and its document production vendor, FTI, worked through nights and weekends to make the data available as soon as possible. Further complicating matters, technical issues arose in extracting the bulk of Custodial Files from a server.[2] Nonetheless, AZ yesterday received the full universe of culled and processed documents that would enable it to complete sampling of Plaintiffs' latest search terms so that terms returning large numbers of irrelevant document hits - in general or for certain Custodians - can be discussed.

Importantly, and ignored by Plaintiffs' latest missive, initial sampling done by AZ last month and ongoing meet and confers have resulted in significant, agreed-upon revisions to the search terms. Plaintiffs waste this Court's (and our) time by seeking court intervention instead of allowing the Court-approved meet and confer process to continue. In short, the process is working and should be continued and the parties can report on the status at the next conference. AZ anticipates that many of Plaintiffs' search terms will be acceptable and thus moot the issue.

Plaintiffs' ludicrous demand that AZ should be required to produce Custodial Files *without* applying search terms because of a server issue and standard processing times for records resulting from Plaintiffs' overbroad terms should be

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they need 120 days (in addition to the 4 months spent negotiating the enabling order) to complete their initial wave of Plaintiff Fact Sheets (*see* Dec. 18, 2018 Status Conf. Tr. at 82:20 - 84:1).

[2] Corporate repositories and databases are designed to perform specific business functions, not to respond to e-discovery in litigation, and as the PSC knows, it is not uncommon for technical issues to arise in e-discovery collections and production.

rejected. As an initial matter, fact depositions are still months away and Plaintiffs have accordingly suffered no prejudice from the pace of discovery. Plaintiffs have no basis for seeking a punitive discovery sanction. *See, e.g.*, *Wachtel v. Health Net, Inc.*, 239 F.R.D. 81, 84 (D.N.J. 2006) (citing *Estate of Spear v. C.I.R.*, 41 F.3d 103, 115 (3d Cir. 1994)) (holding "the party that gains from the sanction must have been at least arguably prejudiced by the misconduct of the other side"). AZ should be given a reasonable opportunity to assess the results and get this right without being bullied by Plaintiffs who have created a moving target by changing the search terms on several occasions, and who have every incentive to manufacture discovery disputes while having, to date, no reciprocal discovery obligation. It is premature and baseless for Plaintiffs to ask to throw out the very concept of search terms here.

B. Document Production Schedule

AZ has produced over 81,000 documents (3.8 million pages) and continues to produce documents on a rolling basis. As Plaintiffs know, many documents require time and effort to produce because the law requires their redaction (*e.g.*, patient identifying and voluntary reporter information). AZ has tried to timely produce documents responsive to Plaintiffs' sweeping requests. Contrary to Plaintiffs' narrative, AZ has been meeting and conferring with Plaintiffs regularly to prioritize document sets of interest.

By way of example, last Tuesday, Plaintiffs inquired when AZ would produce over a dozen categories of documents. We responded to each inquiry and provided an anticipated timeline for production over February and March, and asked to meet and confer about certain overbroad, vague requests. Rather than meet and confer to discuss, Plaintiffs sent their letter requesting Court intervention.

Discovery has been and continues to be completely one-sided. In contrast to AZ's massive discovery efforts, Plaintiffs have produced nothing in this MDL. Not one document showing proof of use or proof of injury. Instead, as AZ forewarned, Plaintiffs try to manufacture discovery disputes and demand unreasonable and unfettered discovery from AZ. Such gamesmanship must be stopped.

C. The Manner in which Documents are Produced

As Plaintiffs' letter notes, AZ produced the applicable IND and NDA submissions and portions of the regulatory file in a prior litigation, and many of these documents were produced to Plaintiffs' counsel last June. For more than 8 months, until last week, Plaintiffs did not raise this issue. Nevertheless, during the parties' February 8 meet and confer, we explained that AZ and FTI were investigating and

that resolution was a top priority. We explained that the production was not nefarious; simply that, over the decades, AZ utilized several different software applications for its submissions to the FDA, which created technical limitations and complicated AZ's ability to produce regulatory files in the manner requested. The law is clear that a producing party is obligated only to produce documents as they exist in the ordinary course of business, and not to produce documents to the receiving party's liking. *See, e.g.*, *In Re G-I Holdings Inc.*, 218 F.R.D. 428, 439 (D.N.J. 2003) ("If the producing party produces documents in the order in which they were kept in the usual course of business, [Rule 34] imposes no duty to organize and label the documents. The duty to organize and label only attaches when the responding party cannot or does not produce the documents as they were kept in the usual course of business"). While AZ's investigation continues, it appears that the documents may have been produced as maintained on AZ's server, in which case Plaintiffs have received the documents as they are held. Further, AZ is not obligated to undertake any efforts to redo prior discovery pursuant to Footnote 1 of the ESI Order which states, "The Parties acknowledge that defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca") have previously collected, processed and produced Documents in another litigation involving Nexium and Prilosec. AstraZeneca will produce previously produced Documents of interest (i.e. INDs, NDAs)…AstraZeneca shall not be required or obligated to redo prior discovery to the extent there are differences with this Protocol."

Despite having no obligation to do so, AZ has nevertheless agreed to allocate considerable resources to investigate and (if feasible) resolve the issues raised by Plaintiffs, including options that would assist Plaintiffs in reorganizing the IND and NDA documents. Unfortunately, despite AZ's immediate response to Plaintiffs complaint (which was just raised last week), Plaintiffs refused to work cooperatively on a solution and instead ask the Court to prematurely intervene. While AstraZeneca agrees that discovery should be a cooperative process and has painstakingly endeavored to fulfill its end of the bargain, Plaintiffs have not. As Plaintiffs suggest, the discovery process should be about cooperation, not a game of "gotcha."

D. Plaintiffs' Request for Bi-Weekly Telephonic Discovery Conferences

Given all of the foregoing, and in light of the fact that Plaintiffs' complaints are not yet ripe, bi-weekly discovery calls are unnecessary. Cynically, such calls seem like another attempt by Plaintiffs for a platform to create discovery issues on a rolling basis, subject Defendants to unreasonable and arbitrary deadlines, dictate Defendants' discovery all while having no reciprocal obligations themselves, and avoid any discussion about the merit of the claims and defenses in the litigation.

Respectfully submitted,

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